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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,683	03/15/2002	Gary Karlin Michelson	101.0042-05000	7210
22882	7590	09/28/2007		
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			EXAMINER TYSON, MELANIE RUANO	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 09/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/098,683	MICHELSON, GARY KARLIN	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-65,67-90 and 92-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-65,67-90 and 92-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/18/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 June 2007 has been entered.

Response to Arguments

2. The terminal disclaimer filed on 25 June 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,758,849 and 6,364,880 has been reviewed and is accepted. The terminal disclaimer has been recorded.

3. Applicant's arguments filed 18 June 2007 have been fully considered but they are not persuasive. Applicant argues that amended independent claim 54 requires a liquid fusion promoting material and a solid fusion promoting material, amended independent claim 79 requires bioactive and bioresorbable materials, and Ray does teach or suggest these new limitations. However, the bone growth promoting materials as claimed, such as hydroxyapatite, bone morphogenetic protein, and tricalcium phosphate are well known in the art for use in promoting new bone growth. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the bone growth promoting materials as claimed in Ray's implant in order to

promote new bone growth. Furthermore, these materials are inherently bioactive and/or bioresorbable materials. With respect to the liquid and solid fusion promoting materials, these limitations are new matter (see rejection below), and thus Applicant's arguments are moot.

Specification

4. The amendment filed 18 June 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In one embodiment, the bone growth promoting material includes a liquid fusion promoting material and a solid fusion promoting material other than bone provided in at least one portion of the hollow interior to promote growth from adjacent vertebral body to adjacent vertebral body through the implant (refer to amended abstract).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-65, 67-78, and 104-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. Applicant failed to disclose a liquid fusion promoting material and a solid fusion promoting material at the time the application was filed (see claims 54, 67, and 104-106). Applicant simply disclosed bone fusion promoting material, such as hydroxyapatite, tricalcium phosphate, and bone morphogenetic protein. Therefore, claims 54-65, 67-78, and 104-106 contain new matter.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 54-65, 67-90, and 92-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray et al. (5,026,373).

Ray discloses a spinal fusion implant comprising upper and lower surfaces having openings there through, a hollow interior for holding bone graft or bone growth promoting material, an insert end and a trailing end having a rear wall (fig. 1 and 5) and the implant being made from the material as claimed. Ray also discloses the hollow interior having an interior surface with a total surface area about 75% (inherently) and 25% of area perforated (cols. 9-10). Although Ray does not disclose bone growth promoting material being bone morphogenetic protein, hydroxyapatite, hydroxyapatite tricalcium phosphate, or a combination thereof (wherein these materials are inherently bioactive and/or bioresorbable materials), the bone growth promoting materials as claimed are well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the bone growth

promoting materials as claimed in Ray's implant in order to promote new bone growth, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Regarding the bone growth promoting material, it also would have been obvious matter of design choice to employ more than one bone growth promoting material in the Ray implant, since applicant has not disclosed that having two different growth promoting materials would solve a stated problem or is used for any particular purpose, and it appears that the implant would perform equally well with one or more promoting materials.

Regarding coating a bone implant, coating a bone implant with the bone growth promoting material is also well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the Ray implant with bone growth promoting material in order to provide a better surface for new bone to growth into the implant and forming bone fusion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
September 18, 2007



(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER